

Attorney Docket No.: KBI-0015  
Inventors: Ranganathan, Natarajan  
Serial No.: 10/689,359  
Filing Date: October 20, 2003  
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#### REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claims 1, 2, and 8-10 have been amended. Claim 11 has been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### I. Rejection of Claims Under 35 U.S.C. §103

Claims 1-3 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,902,578 (Halpin-Dohnalek et al.) for the reasons of record. Applicant respectfully disagrees with this rejection.

As indicated by the Examiner, Halpin-Dohnalek et al. teach a nutritional formula comprising *Lactobacillus reuteri*, *Lactobacillus acidophilus*, and *Bifidobacterium infantis*. See column 3, lines 42-46. In contrast, the present disclosure teaches that *Streptococcus thermophilus* advantageously survives and utilizes or degrades urea at pH ranges of between 5 and 6.5, as typically found in the small intestine. This is of benefit to individuals that have or are prone to the accumulation of toxic nitrogenous waste products. See the paragraph spanning pages 8 and 9 of the present specification. Accordingly, in the interest of facilitating the prosecution of this application, Applicant has amended the claims to highlight the use of *Streptococcus thermophilus* in the compositions and methods of the present invention. Support for this amendment is found throughout the specification and in claims 2 and 10 as originally filed. In light of this amendment, claim 2 has been amended to remove

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reference to *S. thermophilus* and provide the listed probiotic bacteria in conjunction with the *S. thermophilus*.

The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), stated that three factual inquiries underpin any determination of obviousness:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Because Halpin-Dohnalek et al. do not teach or suggest a composition containing *Streptococcus thermophilus*, this reference cannot be held to make the present invention obvious under § 103. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1, 3-5, 7, 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,744,134 (Paul) for the reasons of record. Applicant respectfully traverses this rejection.

Paul teaches that a composition composed of the beneficial human intestinal microorganisms, lactobacilli and bifidobacteria. See abstract and column 4, lines 21-29. In contrast, the amended claims read on compositions containing *Streptococcus thermophilus*. Because Paul does not teach or suggest a composition containing *Streptococcus thermophilus*, this reference

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does not provide all claim limitations and, therefore, cannot be held to make the present invention obvious under § 103. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,518,740 (Costanzo et al.). It is suggested that Costanzo et al. teach a yogurt composition comprising *L. bulgaricus* (probiotic), whole milk (milk proteins), and dextrose (carbohydrate) and soy lecithin (fat). The Examiner acknowledges that Costanzo et al. do not teach the claimed amounts of bacteria; however, suggests that the composition of the yogurt can be varied. Applicant respectfully disagrees with this rejection.

Applicant maintains that the yogurt-based freeze-dried foodstuffs of Costanzo et al. are not disclosed as having any therapeutic benefit and no specific teaching is offered for providing high numbers of CFUs of bacterial. However, in the interest of facilitating the prosecution of this application, Applicant has canceled claim 11, reserving the right to file continuing applications on the canceled subject matter. In light of this amendment, this rejection is moot and it is therefore respectfully requested that this rejection be withdrawn.

Claims 1-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Halpin-Dohnalek and Paul. The Examiner acknowledges that the cited references do not teach all the ingredients together in a single composition in the claimed amounts with the claimed water activity. It is suggested, however, that it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known

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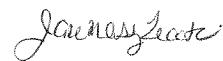
benefit, as disclosed in the cited references. Applicant respectfully traverses this rejection.

As indicated above, Halpin-Dohnalek and Paul teach compositions containing *Lactobacillus sp.* and *Bifidobacterium sp.* However, neither of the cited references teaches a composition containing *Streptococcus thermophilus* as set forth in the claims as currently presented. Because the combined teachings of the cited references fail to teach all the limitations of the claims as required under § 103, these references cannot be held to make the present invention obvious. It is therefore respectfully requested that this rejection be withdrawn.

## II. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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